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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/009,809

04/26/2002

Ronit Eisenberg

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EXAMINER

DAHLE, CHUN WU

ART UNIT

PAPER NUMBER

1644

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/009,809	<b>Applicant(s)</b> EISENBERG ET AL.	
	<b>Examiner</b> CHUN DAHLE	<b>Art Unit</b> 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 06/12/08 and 20 November 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 63-70 and 72-78 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 63-70 and 72-78 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. In view of the Appeal Brief, filed on June 12, 2008, that raises issue (copending USSN 11/495,625 having claims overlapping with the instant application) that has not been considered previously, PROSECUTION IS HEREBY REOPENED. A New Ground of rejection has been set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

2. In view of the New Ground of Rejection presented below, the present Office Action is made NON-FINAL.

3. In view of appellant's Terminal Disclaimer filed on September 25, 2008, the prior nonstatutory obviousness-type double patenting rejection against claims 1-44 of US Patent 7,112,568 has been withdrawn.

4. It is noted that appellant appears to inadvertently miss the outstanding rejection under judicially created doctrine of obviousness-type double patenting over USSN 11/214,588 (see amended page 6 of the Brief filed on November 20, 2008). As such, the Appeal Brief would have been considered non-compliant. Appellant should respond to all of the rejections of record

Art Unit: 1644

including the provisional double patenting rejections; otherwise any such ground of rejection not responded will be summarily sustained by the Board. See MPEP 1205.02.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 63, 66-70, and 72-78 stand rejected under **35 U.S.C. 103(a)** as being unpatentable over Holgate et al. (British Medical Bulletin. 1992. 48;1:40-50, of record) in view of Adridor et al. (Science 1993. 262:1569-1572, of record) and Lin et al. (US Patent 5,807,746, of record) for the same reasons of record.

Appellant's arguments field in the Brief on Appeal, filed on June 12, 2008, have been fully considered but have not been found convincing essentially for the reasons of record.

See the previous Office Action, mailed on November 29, 2007, for more complete analyses.

7. Claims 64 and 65 stand rejected under **35 U.S.C. 103(a)** as being unpatentable over Holgate et al. (British Medical Bulletin. 1992. 48;1:40-50, of record) in view of Adridor et al. (Science 1993. 262:1569-1572, of record) and Lin et al. (US Patent 5,807,746, of record) as

Art Unit: 1644

applied to claim 63 above, further in view of Avruch et al. (US Patent 6,103,692, of record) and Jackson et al. (J. Am. Chem. Soc. 1994. 116:3220-3230, of record) for reasons of record.

Appellant's arguments field in the Brief on Appeal, filed on June 12, 2008, have been fully considered but have not been found convincing essentially for the reasons of record.

See the previous Office Action, mailed on November 29, 2007, for more complete analyses.

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Art Unit: 1644

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. This is a **New Ground of Rejection**. Claims 63-70 and 72-78 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-24 of copending USSN 11/495,625.

Given the CIP relationship between the instant application and USSN 11/495,625 and Pfizer Inc. v. Teva Pharmaceuticals USA Inc., 86 USPQ2d 1001 (Fed. Cir. 2008), the following obviousness-type double patenting rejection is set forth.

The instant claims directed to a method of inhibiting mast cell degranulation by administering a therapeutic agent comprising a first segment having amino acid sequence of AAVALLPAVLLALLAP (SEQ ID NO:3) linked via a second segment having the amino acid sequence of KNNLKECGLY (SEQ ID NO:1) are not patentably distinct from the copending claims drawn to the same or nearly the same therapeutic agent since the instant method claims merely recite methods of administering "a pharmaceutically effective amount of a therapeutic agent" found in claims 1-24 of the copending USSN 11/495,625 and since the copending method claims merely claims particular use of the therapeutic agent described in the copending application. Therefore, the instant claims would anticipate the copending claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 63-70 and 72-78 stand provisionally rejected on the ground of **nonstatutory obviousness-type double patenting** as being unpatentable over claims 1 and 3-15 of the copending USSN 11/214,588 for reasons of record.

Art Unit: 1644

Given that a terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) has not been filed; the rejection on the basis of double patenting will be maintained until such a time that allowable subject matter is determined or a terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) is timely filed.

11. Conclusion: no claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun Crowder whose telephone number is (571) 272-8142. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chun Dahle

Patent Examiner

December 31, 2008

/Maher M. Haddad/

Primary Examiner,

Art Unit 1644

Application/Control Number: 10/009,809

Page 7

Art Unit: 1644

/Eileen B. O'Hara/

Supervisory Patent Examiner

Art Unit 1644